

Elective Angio Study: News Summary Nov 14-16, 2007

Burlington County Times - 11/16/07

Brief:

A decision yesterday allowing some state hospitals to perform an elective heart procedure as part of a medical trial is good news for Virtua West Jersey Hospital and could be bad news for Deborah Heart and Lung Center

Link:

<http://www.phillyburbs.com/pb-dyn/news/112-11162007-1441966.html>

Text:

State board adopts new angioplasty guidelines

By JASON HARRIS

Burlington County Times

A decision yesterday allowing some state hospitals to perform an elective heart procedure as part of a medical trial is good news for Virtua West Jersey Hospital and could be bad news for Deborah Heart and Lung Center.

The state Health Care Administration Board in Ewing voted 6-1 yesterday to adopt new rules allowing hospitals that do not provide on-site heart surgery to perform elective angioplasties as part of a medical trial called the Cardiovascular Patient Outcomes Research Team.

The trial, directed by Johns Hopkins University, is examining whether it is safe for such hospitals to perform elective angioplasties.

Sue Bonfield, vice president of legal and regulatory affairs at Deborah, downplayed the potential business impact of yesterday's ruling. "It's a disappointment for the state and for the people of the state," she said.

Bonfield said hospitals like Virtua West Jersey, which previously have not been allowed to perform elective angioplasties by law, can't provide the same level of care as hospitals like Deborah, which perform hundreds of angioplasties each year.

"What was just approved today is allowing hospitals who do a very few of these (procedures) to hold themselves out as doing them in the same way as hospitals who do 10 times as many," she said.

However, Deborah President and CEO John Ernst has previously said that permitting nearby hospitals to perform angioplasties could cost Deborah millions of dollars in lost patients.

During an angioplasty, a doctor inserts a small balloon into a blocked artery. The balloon is inflated to remove the blockage and widen the artery. A small metal coil called a stent is often inserted into the cleared artery after the angioplasty to help prop the artery open and decrease the chance of it narrowing again.

More than 1 million angioplasties are conducted in the United States each year, according to The Mayo Clinic. “This is a demonstration project that will allow us once and for all to know with reliable data, scientific data, that the program is safe or not safe,” said Jim Dwyer, chief medical officer for Virtua Health, after the vote. “It is our belief it is safe.”

Dr. Robert Singer, chief of cardiology at Virtua West Jersey, said the 18 hospitals in New Jersey opposed to the trial — which include Deborah, Cooper University Hospital in Camden and Our Lady of Lourdes Medical Center in Camden — should welcome the chance to prove they provide superior care.

“If they're truly excellent, the stats will show it,” he said. “Let the data speak for itself.”

Hospitals interested in taking part in the study must apply for certificates of need from the state. The board had to adopt new regulations after the Supreme Court threw out the previous rules for application May 31.

Yesterday's decision by the Health Care Administration Board means New Jersey hospitals will still participate in the study, and increases the maximum number of hospitals that can participate from nine to 12.

Hospitals interested in joining the study must apply for certificates of need. That process takes several months.

In its ruling in May, the court ordered the hospitals currently in the study, including Virtua West Jersey, to shut down their programs by Nov. 30. The Supreme Court has not acted on an appeal filed by Virtua, and unless the court reverses itself or extends the deadline, the existing programs will have to shut down next week.

Dwyer is hoping that doesn't happen.

“To continue access for patients and assuring none of the current data becomes damaged, we hope to be able to continue without interruption,” he said.

The Star-Ledger – 11/16/07

Brief:

A state health advisory board yesterday approved regulations enabling New Jersey's continued participation in a national study gauging the safety of elective angioplasty in community hospitals without cardiac surgery available as back up.

After listening to two hours of testimony about the study currently involving nine New Jersey hospitals, members of the Health Care Administration Board voted 6-1, with one abstention, to adopt revised rules developed by the state health department.

Link:

<http://www.nj.com/news/ledger/jersey/index.ssf?/base/news-8/1195192580111370.xml&coll=1&thispage=2>

Text:

State health board clears rules for angioplasty study

Friday, November 16, 2007

BY ANGELA STEWART

Star-Ledger Staff

A state health advisory board yesterday approved regulations enabling New Jersey's continued participation in a national study gauging the safety of elective angioplasty in community hospitals without cardiac surgery available as back up.

After listening to two hours of testimony about the study currently involving nine New Jersey hospitals, members of the Health Care Administration Board voted 6-1, with one abstention, to adopt revised rules developed by the state health department.

The State Supreme Court last spring threatened to disallow New Jersey's continued participation in the Johns Hopkins University study if department rules were not re-written by Nov. 30th to allow such a program to exist. The ruling came after three South Jersey cardiac centers -- Cooper University Hospital, Our Lady of Lourdes Medical Center and Deborah Heart and Lung Center -- challenged the so-called "demonstration program," contending state regulations prohibited state hospitals from performing elective angioplasty without heart surgeons on site.

In addition to directing the department to re-write its regulations, the court also directed officials to issue a new call for applications for the program, which the department did last week.

Joseph A. Roth, the lone board member voting against adoption of the regulations yesterday and who raised questions about monitoring of patient safety, said he remain "unconvinced" the study should move forward.

But board Chairman Michael Baker said he was convinced there was a proper balance between advancing science and patient safety.

A total of 27 states and many European countries already permit cardiologists to perform elective angioplasty in small, community hospitals that don't have cardiac surgeons on site. In New Jersey, these hospitals must have transfer agreements with a cardiac center to participate in the study.

"Nothing is without risks. If we didn't take risks, there would be no new discovery," Baker said.

The Supreme Court could rule as early today on a motion filed by Virtua Health, one of the participating hospitals, on whether it and the other hospitals in the study can continue performing elective angioplasty while the state restarts the application process.

The process, which will require all nine participating hospitals to re-submit applications, is expected to drag on until next summer.

Other hospitals that were rejected the first time around can reapply if they meet the program criteria, with Dec. 18 the application deadline.

"I feel we are obligated to finish this trial," said Thomas Aversano, the Johns Hopkins professor leading the study, who after the vote said he was "totally perplexed" about the opposition that has emerged in New Jersey.

The nine hospitals involved in the study performed 1,101 elective angioplasties between April 1, 2006 and June 30, 2007, resulting in four deaths, according to data released this week by the health department.

The son of one of those four patients pleaded with the board yesterday to "immediately stop this trial."

"When my father got out of the cath lab, he was screaming in pain," said Arup Roy, a physician whose 84-year-old father died at Virtua Hospital in Marlton days after undergoing an angioplasty last fall.

Virtua officials have said the man's death was unrelated to the procedure, noting he had cancer.

Representatives who spoke on behalf of Cooper, Our Lady of Lourdes and Deborah -- all of whom oppose the study -- questioned whether the program's oversight was rigorous enough. Some speakers also pointed out that not all the hospitals met the study's volume requirements, a safeguard for helping to assure quality outcomes.

"There's no accounting for the patients that died," said Gary Young, Cooper's director of government relations.

Besides the death at Virtua, two patients died at Holy Name in Teaneck and one at Robert Wood Johnson University Hospital Hamilton, according to the data, which have not been adjusted to reflect the medical risk of each patient.

Gannett Newspapers (APP, Courier Post, Home News Tribune, The Daily Record, The Daily Journal, Ocean County Observer) – 11/16/07

Brief:

Before a crowded and combative room of health-care professionals, a state health department board Thursday approved amending state regulations to allow hospitals in a demonstration project to perform elective angioplasties without on-site surgical teams.

Link:

<http://www.c-n.com/apps/pbcs.dll/article?AID=2007711160340>

Text:

Hospitals can join angioplasty study
State board OKs relaxing regulations.

By MICHAEL RISPOLI

GANNETT STATE BUREAU

EWING -- Before a crowded and combative room of health-care professionals, a state health department board Thursday approved amending state regulations to allow hospitals in a demonstration project to perform elective angioplasties without on-site surgical teams.

The approval -- by a 6-1 vote, with one abstention -- will allow hospitals to apply in December to join the ongoing three-year study sponsored by the Johns Hopkins School of Medicine in six states. Nine hospitals in the state already had been participating before a state Supreme Court ruling in May said the department had until Nov. 30 to change regulations in order for the procedures to continue beyond that date.

The goal of the study is to determine whether the procedure -- in which a tiny balloon is inserted into an artery to widen a blocked vessel -- is equally safe when performed at a hospital without surgical backup, as it currently is done at 18 hospitals with surgical staffs. Twenty-seven states allow the procedure without on-site surgical backup.

Michael Baker, chairman of the Health Care Administration Board, said an appropriate balance was struck between the unproven procedure and the possible benefits that could be reaped as a result of expanding access to it.

"Nothing is without risk. If we didn't take risks as a society or in medicine, there would be no advancements and no new discoveries," Baker said.

Board member Joseph Roth, who cast the lone vote against the new rules, said he is "unconvinced" the study should go forward.

"I appreciate the scientific aspects of it, but I'm also thinking of the public health needs for the state," Roth said.

The American Heart Association and the American College of Cardiology do not support the procedure without on-site surgical backup but have said they could change their position if data comes out proving it is safe.

The nine hospitals in the demonstration project are Bayonne Medical Center, Holy Name Hospital, Monmouth Medical Center, Muhlenberg Regional Medical Center, Raritan Bay Medical Center, Robert Wood Johnson University Hospital-Hamilton, Somerset Medical Center, Trinitas Hospital and Virtua West Jersey Hospital-Marlton.

The state Supreme Court could rule the nine hospitals have to stop practicing the procedure until the new licensing regulations are adopted Dec. 17. Virtua asked for a clarification of the ruling and permission to continue practicing the procedure in the meantime. The court is slated to hear arguments Nov. 27.

Hospitals in favor of the study said it provides patients with more access to the procedure, while opponents say performing the procedure without a backup surgical team is unethical and puts patients at risk. Both sides accuse the other of choosing finances over patient care.

Richard Miller, president and chief executive officer of Virtua, said the data will improve the long-term welfare of the public.

"This needs to be determined now so that we are prepared moving into the future," Miller said.

Though fewer in number, opponents were loud in their opposition before the board.

"There are serious ethical problems with approving the revised regulations because I would argue there has not been a fair evaluation of patient safety," said Gary Young, executive vice president of government relations for Cooper University Hospital.

The state Department of Health and Senior Services strongly pushed for the board to approve the measures.

The Philadelphia Inquirer – 11/16/07

Brief:

A state administrative board voted yesterday to let a handful of hospitals continue to perform a heart procedure without the benefit of full open-heart surgery programs, an issue that has led to controversy and intense lobbying by competing hospitals in South Jersey.

Link:

http://www.philly.com/inquirer/local/20071116_Board_OKs_heart_procedure.html

Text:

Board OKs heart procedure

By Don Sapatkin

Inquirer Staff Writer

A state administrative board voted yesterday to let a handful of hospitals continue to perform a heart procedure without the benefit of full open-heart surgery programs, an issue that has led to controversy and intense lobbying by competing hospitals in South Jersey.

As a practical matter, the new regulations will not clear the way for the community hospitals to keep doing angioplasties until next summer. It is now up to the state Supreme Court to decide whether they can continue past the end of this month, a deadline that the justices set in May.

Virtua-West Jersey Hospital in Marlton is the only hospital in the group that's in South Jersey. Nine hospitals in the state have been allowed to do the procedure as part of a medical study designed to determine whether full surgical backup makes a difference to patient safety and health.

The study, conducted by researchers at Johns Hopkins University, appears to have raised few concerns in North Jersey or in several other states participating in the research. Eleven Pennsylvania hospitals do angioplasty without heart-surgery backup, including five in and around Philadelphia.

But three institutions that offer open-heart surgery in South Jersey - Cooper University Hospital, Our Lady of Lourdes Medical Center, and the Deborah Heart and Lung Center - have strongly opposed the practice.

Coronary angioplasty involves threading a tiny balloon up an artery toward the heart. When it reaches the blockage, the balloon is inflated, unclogging the artery, and a tiny mesh stent is installed, keeping it open.

Joining together as a coalition, the three full-service hospitals have submitted testimony from physicians and others who argue that the community hospitals don't perform enough of the procedures to guarantee the best results, and don't have the on-site surgical programs and expertise to consider a full range of options or to provide good enough backup if something goes wrong.

Virtua and the state Department of Health and Human Services have said the angioplasties are being done safely.

In May, the New Jersey Supreme Court ruled that the proper procedures had not been followed and gave the state until Nov. 30 to issue new rules or to shut down the study.

The passage yesterday of new regulations by the state Health Care Administration Board increases the number of participating hospitals to 12 and requires new applications for all the spots. It also adds a "Certificate of Need" requirement, which would demonstrate that there is sufficient demand for the service.

That would appear to satisfy the court's concerns - except that approvals will take until July to complete.

Virtua has petitioned the court to allow the status quo from Nov. 30 until then.

A court spokeswoman said yesterday that today was the justices' only scheduled conference day before Nov. 30, although others could be added.

"I know that they are aware of that date," she said.

Immediately following the hearing

Courier Post Online – 11/15/07

Brief:

Before a tense, crowded room of health care professionals, a state health department board today approved amending state regulations to allow hospitals in a demonstration project to perform elective angioplasty with no on-site surgical team. The hospitals include Virtua in Marlton.

Link:

<http://www.courierpostonline.com/apps/pbcs.dll/article?AID=/20071115/NEWS01/711150419>

Text:

Virtua OK'd for elective angioplasty project

By MICHAEL RISPOLI
Gannett State Bureau

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The approval - by a 6-1 vote, with one abstention - will allow hospitals to apply in December to join the ongoing three-year study sponsored by the Johns Hopkins School of Medicine. Nine hospitals in the state had already been participating before a state Supreme Court ruling in May said the department had until Nov. 30 to change regulations in order for the procedures to continue.

The goal of the study is to determine whether such a procedure is equally safe when performed at a hospital without surgical backup, as it is currently done at 18 hospitals with surgical staffs.

The hospitals in favor of the study said it provides patients with more access to the procedure, while opponents say performing the procedure without a backup surgical team is unethical and puts patients at risk. Both sides accuse the other of choosing finances over care for the patient.

Michael Baker, chair of the Health Care Administration Board, said there was an appropriate balance between the unproven procedure and the possible benefits that could be reaped as a result of expanding it.

"Nothing is without risk. If we didn't take risk as a society or in medicine, there would be no advancements and no new discoveries," Baker said.

The nine hospitals in the demonstration project are Bayonne Medical Center, Holy Name Hospital, Monmouth Medical Center, Muhlenberg Hospital, Raritan Bay Medical Center, Robert Wood Johnson University Hospital-Hamilton, Somerset Medical Center, Trinitas Hospital and Virtua West Jersey Hospital-Marlton.

Published: November 15, 2007 1:58PM

Asbury Park Press – 11/15/07

Brief:

Before a tense, crowded room of health care professionals, a state health department board Thursday approved amending state regulations to allow hospitals in a demonstration project to perform elective angioplasty with no on-site surgical team.

Link:

<http://www.app.com/apps/pbcs.dll/article?AID=/20071115/NEWS0301/71115034>

Text:

State votes to let elective angioplasty project continue

BY MICHAEL RISPOLI
GANNETT STATE BUREAU

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The Home News Tribune – 11/15/07

Brief:

Before a tense, crowded room of health care professionals, a state health department board Thursday approved amending state regulations to allow hospitals in a demonstration project to perform elective angioplasty with no on-site surgical team.

Link:

<http://www.thnt.com/apps/pbcs.dll/article?AID=/B3/20071115/NEWS0301/71115034>

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The Star-Ledger – 11/15/07

Brief:

A state health advisory board today voted overwhelmingly to approve regulations enabling New Jersey's continued participation in a national study on elective angioplasty.

Link:

http://www.nj.com/news/index.ssf/2007/11/a_state_health_advisory_board.html

Text:

NJ hospitals can continue angioplasty study, board says

by Angela Stewart/The Star-Ledger

A state health advisory board today voted overwhelmingly to approve regulations enabling New Jersey's continued participation in a national study on elective angioplasty.

Members of the Health Care Administration Board voted 6-1, with one abstention, in favor of adopting revised rules developed by state health officials in response to a state Supreme Court last spring. The court had threatened to disallow New Jersey's continued participation in the study if the rules were not re-written by Nov. 30.

There are currently nine community hospitals in New Jersey participating in the study, which is being run by Johns Hopkins University. The aim is to determine whether elective angioplasty performed at community hospitals without cardiac surgeons on hand is as safe and effective as those performed at cardiac centers.

After the program was challenged by three South Jersey cardiac centers that contended state regulations prohibited such a program, the court ruled May 31 that health officials had to revise the rules if they wanted the program to continue. The court also required the department to issue a new call for applications, which it did last week.

Now that the board has voted to adopt the new regulations, the court could rule as early as Friday on whether the nine hospitals can continue their elective angioplasty programs while the new hospital selection process moves forward. One of the nine hospitals -- Virtua Health -- had filed a motion with the court asking for a clarification on the issue.

The new selection process, which will require the nine hospitals currently in the study to re-submit their applications if they wish to continue, is expected to take six months or longer.

The Philadelphia Business Journal – 11/15/07

Brief:

The New Jersey Health Care Administration Board Thursday approved regulations proposed by the New Jersey Department of Health and Senior Services that will enable the state's continued participation in a national demonstration project on elective angioplasty.

Link:

<http://www.bizjournals.com/philadelphia/stories/2007/11/12/daily32.html>

Text:

New Jersey to remain in elective angioplasty study

John George

The New Jersey Health Care Administration Board Thursday approved regulations proposed by the New Jersey Department of Health and Senior Services that will enable the state's continued participation in a national demonstration project on elective angioplasty.

The controversial project, being conducted in six states by cardiologists at Johns Hopkins Medical Institutions in Baltimore, is looking at the safety of having hospitals perform elective angioplasty procedures without on-site open-heart surgery programs.

Among the nine New Jersey medical centers participating in the project is Virtua West Jersey's Marlton hospital.

In May, the state's Supreme Court sided with a group of hospitals that sued the state to block its participation in the project. The hospitals filing the suit, Cooper University Hospital and Our Lady of Lourdes Medical Center in Camden and Deborah Heart and Lung Center in Browns Mills, argued that the state health commissioner did not follow the proper rules in 2005 when issuing certificates-of-need allowing hospitals to participate.

Representatives from Cooper, Lourdes and Deborah spoke at a health care administration board hearing on the matter in July.

They questioned both the need and safety of allowing hospitals to perform elective angioplasties without on-site cardiac surgery, given that there are already 18 hospitals spread throughout the state that perform the procedure and have open-heart surgery programs.

Virtua officials have maintained the hospitals are opposed to the demonstration project because they are worried about losing revenue.

The Supreme Court gave the state health department until Nov. 30 to enact new regulations.

"Today's vote represents a major step forward for patients, hospitals and health-care policy in general in the state of New Jersey," said Richard P. Miller, president and CEO of Virtua Health. "This is an extremely important study, the results of which will be integral to our ability to provide the highest-quality cardiac care to residents of New

Jersey -- now and in the future. The quality and integrity of the project are beyond reproach, and we are gratified that the board has recognized these facts and acted in favor of its continuation."

In September, Virtua filed a motion with the Supreme Court seeking to continue its participation in the project after Nov. 30 if the state had not ruled on new regulations by that time.

The other states participating in the Hopkins study are Alabama, Georgia, Illinois, Ohio and Pennsylvania.

Day before the hearing

The Home News Tribune – Op Ed Piece – 11/14/07

Link:

<http://www.thnt.com/apps/pbcs.dll/article?AID=/20071114/COLUMNISTS/711140400>

Text:

N.J. should continue in project expanding sites for cardiac care

MICHAEL R. D'AGNES

Nine hospitals in New Jersey have the opportunity to help shape the future of cardiac care across the nation. Only one thing may hold them back: a lawsuit by three South Jersey hospitals that are more concerned about their own profits than sound health-care policy and patient care.

Raritan Bay Medical Center is pleased to be among the nine New Jersey hospitals participating in an important demonstration project led by Johns Hopkins Medicine's Cardiovascular Patient Outcomes Research Team (or C-PORT) to compare the outcomes of patients treated with a lifesaving procedure called elective angioplasty at hospitals with cardiac surgery on site versus hospitals that have off-site cardiac surgery backup. Expanding sites allowed to perform elective angioplasty lets patients remain in the continuous care of their trusted primary-care physician and cardiologist.

Raritan Bay Medical Center and all of the institutions participating in the project have met a stringent set of safety and clinical requirements and have been approved for participation by the New Jersey Department of Health and Senior Services. Raritan Bay Medical Center has a long-standing safety record. We have been successfully performing diagnostic angiograms for more than 10 years and emergency angioplasty for more than three years, treating the sickest of patients experiencing acute heart attack. In addition, the project is under continuous review by an independent Data and Safety Monitoring Board made up of scientists, medical experts and ethicists from around the country to ensure that the protocols are safe and that the data collected are accurate. As recently as May 2007, this independent board recommended the continuation of the project under its current protocols.

Yet three South Jersey hospitals — Cooper University Hospital, Deborah Heart and Lung Center, and Our Lady of Lourdes Medical Center — have aggressively sought to prevent the project from being completed, publicly claiming that their concerns center on patient safety. Cooper, Deborah and Lourdes filed suit against the state health department and Virtua Health, one of the demonstration project participants, to stop the study based on procedural issues by claiming that the study was in conflict with an existing state regulation that allowed elective angioplasties to be performed only at hospitals that had cardiac surgery programs. The New Jersey Supreme Court ruled that the state health commissioner did have the right to approve the study, but that the state would have to rewrite the project's regulations to continue beyond Nov. 30.

Continuation of the Johns Hopkins C-PORT-E demonstration project makes sense both from patient care and health policy standpoints. It is good not only for the state of New Jersey, but also for health care nationally. The number of angioplasties performed annually continues to rise as the number of heart surgeries performed falls. According to the American Heart Association, in 2002 an estimated 650,000 angioplasty procedures were performed. This amounts to a 324 percent increase in volume since 1987. As the baby boom generation ages, the incidence of heart disease and the need for angioplasty is expected to grow even more.

Under the existing 20-plus-year-old state regulations that this study is designed to evaluate, cardiologists at hospitals without on-site cardiac surgery backup who see a potentially life-threatening blockage during the diagnostic procedure must withdraw the catheter from the patient, and transfer the patient to another institution where the catheter is reinserted and angioplasty is performed. The Johns Hopkins demonstration project will determine if regulations like these — originally put in place when angioplasty was still in its infancy and without its current record of clinical success — should be revised across the country. Elective angioplasty is already being performed in hospitals without open heart surgery programs in at least 21 states, and in many European countries.

Unless the public makes its voice heard on the continuation of this demonstration project by Nov. 30 — the Supreme Court's deadline — it is possible that New Jersey will be dropped from this important study. For that reason, the nine hospitals have come together to launch a public-education effort to highlight the facts supporting continuation of this vital project.

New Jersey residents have a need to know about this important public health issue, and what it means to their long-term health. On behalf of Raritan Bay Medical Center and all of the New Jersey hospitals participating in the C-PORT-E project, I urge you to visit www.HealthyHeartNJ.org to learn more about this important issue.